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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,462	08/15/2003	Daniele Piomelli	02307E-125510US	2152

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EXAMINER	
THOMAS, TIMOTHY P	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/642,462	PIOMELLI ET AL.	
	Examiner	Art Unit	
	TIMOTHY P. THOMAS	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-22 and 25-46* is/are pending in the application.

4a) Of the above claim(s) *32 and 34-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-22,25-31 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/27/2008 has been entered.

Election/Restrictions

2. The subject matter under examination is expanded to include the PPARα agonist compound Palmitoylethanolamide (PEA), which reads on claim 20, but not claim 31.

Priority

3. The amended phrase "wherein the PPARα agonist and a cannabinoid CB1 receptor antagonist are present in mutually synergistic amounts for reducing the food consumption" does not have 112 1st paragraph support in the priority document, U.S. Application No. 60/405,047, because the genus term "PPARα agonists" is not disclosed, nor are a sufficient number of examples present to demonstrate possession of the entire genus in the priority disclosure. It is noted that paragraph 15 of 60/405,047 does provide language for a subgenus within the broader genus of PPARα agonists, i.e., "OEA-like appetite reducing compounds" in combination with cannabinoid CB1 receptor antagonists that are alleged to act synergistically; additionally the formula recited in

instant claim 20 and the compound oleoylethanolamide of instant claim 17 are disclosed in the specification of the priority document.

4. Therefore, claim 16 is accorded the filing date of 8/15/2003, but not the priority date of 8/20/2002.

Response to Arguments

5. Applicants' arguments, filed 10/27/2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

6. Applicant's arguments, see p. 10, last two paragraphs, filed 10/27/2008, with respect to the rejection under 35 USC 103 have been fully considered and are persuasive. The rejection of claims 16-22, 25-31 and 33 has been withdrawn.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 16-22, 25-31 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The disclosure describes one set of concentrations of OEA and rimonabant for which "synergistic amounts for reducing food consumption" have been demonstrated, now required by the claims, specifically for the dosage amounts of 1 mg/kg OEA and 0.3 mg/kg Rimonabant (SR141716A). While it is acknowledged that a small range around each of these concentrations would be expected to also be synergistic, other possible dose concentrations have not been named or described to demonstrate that applicant was in possession at the time of filing of the genus of all "synergistic amounts [of the combination of OEA and rimonabant] for reducing the food consumption". Additionally, no such synergistic dosage combination has been disclosed for any combination of PEA and rimonabant. Therefore, applicant is not in possession of the any synergistic amounts of the combination of PEA and rimonabant or of the entire genus of synergistic amounts of OEA and rimonabant.

It is noted that a claim limited to the dosage amounts of 1 mg/kg OEA and 0.3 mg/kg Rimonabant (SR141716A) in combination would overcome this rejection.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc.,

> that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*,

the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163. While all of the factors have been considered, a sufficient amount for a *prima facie* case are discussed below.

In the instant case, the claims are drawn to a pharmaceutical composition for reducing food consumption in a mammal, said composition comprising a PPARα agonist (a genus including OEA and PEA) and a cannabinoid CB1 receptor antagonist (a genus including rimonabant) wherein the PPARα agonist and a cannabinoid CB1 receptor antagonist are present in mutually synergistic amounts for reducing the food consumption.

(1) Level of skill and knowledge in the art:

The level of skill and knowledge in the art are high. However, such knowledge does not generally include the ability to predict a priori which combinations of compounds will have synergistic properties.

(2) Partial structure:

Many different possible compounds have been disclosed including the compounds under examination, OEA, PEA and rimonabant.

(3) Physical and/or chemical properties and (4) Functional characteristics:

The compounds of the invention are useful in reducing the amount of food consumed by animals; the allegation is made that combinations of such compounds are mutually synergistic.

(5) Method of making the claimed invention:

Applicant has only provided evidence demonstrating one specific dosage set of the compounds OEA and rimonabant that possess the required claimed property of mutual synergism. No other method of making such a combination has beedn disclosed.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claim(s) 16-22, 25-31 and 33 is/are broad and generic, with respect to all possible combinations of compounds encompassed by the claims. The possible structural variations are limitless to any possible combination of dosages of any possible combination of two compounds within the scope of the claims. Although the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond those compounds specifically disclosed in the examples in the specification.

Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus. While having written description of the dosage amounts of 1 mg/kg OEA and 0.3 mg/kg Rimonabant (SR141716A), the specification does not provide sufficient descriptive support for the myriad of dosage combinations of the compounds embraced by the claims.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claim Rejections - 35 USC § 103

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gomez et al. ("A Peripheral Mechanism for CB1 Cannabinoid Receptor-Dependent Modulation of Feeding"; 2002 Nov; The Journal of Neuroscience; 22(21): 9612-9617; IDS 3/17/2004 reference 72).

It is noted that claim 16 has been accorded the filing date of 8/15/2003, for which Gomez is prior art, based on the broader genus of claim 16 than is disclosed in the priority document, as outlined above.

Gomez teaches oleoyethanolamide and SR14716A (rimonabant) synergistically inhibit feeding (p. 9615, 3rd paragraph, p. 9616, Figure 4); 0.3 mg/kg SR14716A with 1 or 5 mg/kg display synergy (Fig.4). Gomez does not teach a pharmaceutical composition that contains both OEA and rimonabant. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine OEA and rimonabant at the amounts for which synergy is taught by Gomez into a single pharmaceutical composition for reducing food consumption in a mammal, giving the composition of the claim. The motivation would have been simpler dosing of both components in a single composition.

Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY P. THOMAS whose telephone number is (571)272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Timothy P Thomas/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614